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Term: method$ same implant$ same vertebr$ adj3 disc and distract$ and remov$ and allogra$

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L5	method$ same implant$ same vertebr$ adj3 disc and distract$ and remov$ and allogra$	6	L5
L4	method$ same implant$ same vertebr$ adj3 disc and distract$ and remov$	36	L4
L3	method$ same implant$ and vertebr$ adj3 disc and distract$ and remov$	109	L3
L2	(((623/908)!.CCLS.)) and disc and vertebrae	4	L2
L1	((623/902)!.CCLS.) and disc and vertebrae	1	L1

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Term: (temporar$ or trial) same spacer and disc same implant and allograf$

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L3	(temporar$ or trial) same spacer and disc same implant and allograf$	7	L3
L2	(temporar$ or trial) same spacer and disc same implant	13	L2
L1	(temporar$ or trial) and spacer and disc same implant	62	L1

END OF SEARCH HISTORY

DOCUMENT-IDENTIFIER: US 5484437 A
TITLE: Apparatus and method of inserting spinal implants

Abstract Paragraph Left (1):
Apparatus and a method of inserting spinal implants is disclosed in which an intervertebral space is first distracted, a hollow sleeve having teeth at one end is then driven into the vertebrae adjacent that disc space. A drill is then passed through the hollow sleeve removing disc and bone in preparation for receiving the spinal implant which is then inserted through the sleeve.

Brief Summary Paragraph Right (2):
The present invention relates to artificial fusion implants to be placed into the intervertebral space left remaining after the removal of a damaged spinal disc and specifically to the apparatus for and method of, inserting the implants.

Brief Summary Paragraph Right (5):
The purpose of the present invention is to provide an implant, and the apparatus and method of inserting the implant within the intervertebral space left after the removal of the disc material and permanently eliminate all motion at that location. To do so, the device of the present invention is space occupying within the disc interspace, rigid, self-stabilizing to resist dislodgement, stabilizing to the adjacent spinal vertebrae to eliminate local motion, and able to intrinsically participate in a vertebra to vertebra bony fusion so as to assure the permanency of the result.

Brief Summary Paragraph Right (6):
At present, following the removal of a damaged disc, either bone or nothing is placed into the remaining space. Placing nothing into this space allows the space to collapse which may result in damage to the nerves; or the space may fill with scar tissue and eventually lead to a reherniation. The use of bone to fill the space is less than optimal in that bone obtained from the patient requires additional surgery and is of limited availability in its most useful form, and if obtained elsewhere, lacks living bone cells, carries a significant risk of infection, and is also limited in supply as it is usually obtained from accident victims. Furthermore, regardless of the source of the bone, it is only marginal structurally and lacks a means to either stabilize itself against dislodgement, or to stabilize the adjacent vertebrae.

Brief Summary Paragraph Right (13):
In summary, these devices resemble the present invention only in that they are placed within the intervertebral space following the removal of a damaged disc. In that they seek to preserve spinal motion, they are diametrically different from the present invention which seeks to permanently eliminate all motion at that spinal segment.

Brief Summary Paragraph Right (14):
A second related area of prior art includes those devices utilized to replace essentially wholly removed vertebrae. Such removal is generally necessitated by extensive vertebral fractures, or tumors, and is not associated with the treatment of disc disease. While the present invention is to be placed within the disc space, these other vertebral devices cannot be placed within the disc space as at least one vertebra has already been removed such that there no longer remains a "disc space". Furthermore, these devices are limited in that they seek to perform as temporary structural members mechanically replacing the removed vertebrae (not a removed disc), and do not intrinsically participate in supplying osteogenic material to achieve cross vertebrae bony fusion. Therefore, unlike the present invention which provides for a source of osteogenesis, use of this group of devices must be accompanied by a further surgery consisting of a bone fusion procedure utilizing

conventional technique. This group consisting of vertebral struts rather than disc replacements would include the following:

Brief Summary Paragraph Right (17):
U.S. Pat No. 4,554,914 to KAPP--describing a large distractible spike that elongates with a screw mechanism to span the gap left by the removal of an entire vertebra and to serve as an anchor for acrylic cement which is then used to replace the missing bone (vertebrae).

Brief Summary Paragraph Right (18):
U.S. Pat No. 4,636,217 to OGILVIE--describing a vertebral strut mechanism that can be implanted after at least one vertebrae has been removed and consists of a mechanism for causing the engagement of screws into the vertebrae above and the vertebrae below the one removed.

Brief Summary Paragraph Right (19):
In summary, this second group of devices differs from the present invention in that they are vertebral replacements struts, do not intrinsically participate in the bony fusion, can only be inserted in the limited circumstances where an entire vertebra has been removed from the anterior approach, and are not designed for, or intended to be used for the treatment of disc disease.

Brief Summary Paragraph Right (26):
Another area of related prior art to be considered is that of devices designed to be placed within the vertebral interspace following the removal of a damaged disc, and seeking to eliminate further motion at that location.

Brief Summary Paragraph Right (33):
3. Disc removal--The BAGBY invention requires the complete removal of the disc prior to the drilling step, whereas the present invention eliminates the laborious separate process of disc removal and efficiently removes the disc and prepares the vertebral end plates in a single step.

Brief Summary Paragraph Right (34):
4. Time required--The present invention saves time over the BAGBY invention since time is not wasted laboring to remove the disc prior to initiating the fusion. Also, with the present invention the procedure is performed through a system of guarded instrumentation, time is not wasted constantly placing and replacing various soft tissue retractors throughout the procedure.

Brief Summary Paragraph Right (35):
5. Implant stability--Dislodgement of the implant would be a major source of device failure (an unsuccessful clinical result), and might result in patient paralysis or even death. As discussed, the BAGBY device lacks any specific means of achieving stability and since it is pounded in against resistance to achieve vertebral distraction, and is susceptible to forceful dislodgement by the tendency of the two distracted vertebrae, to return to their original positions squeezing out the device. The present invention, however, is screwed into place. As there is no unscrewing force present between the vertebrae, compression alone cannot dislodge the implant. The implant is inherently stable by its design. Furthermore, the threads of the present invention are highly specialized in that they are periodically interrupted so that the tail ends of each of the tabs so formed are blunted and twisted so as to resist accidental unscrewing. The removal of an implant with such "locking threads" requires the use of a special extractor included within the instrumentation. The stability of the present invention is still further enhanced, again in contradistinction to the BAGBY device, by the presence of a "bone ingrowth" surface texturing, which both increases the friction of the fit and allows for the direct growth of the vertebral bone into the casing of the implant itself.

Brief Summary Paragraph Right (48):
In 1956, Ralph Cloward developed a method and instruments which he later described for preparing the anterior aspect (front) of the cervical spine, and then fusing it. Cloward surgically removed the disc to be fused across and then placed a rigid drill guide with a large foot plate and prongs down over an aligner rod and embedded said prongs into the adjacent vertebrae to maintain the alignment so as to facilitate the reaming out of the bone adjacent the disc spaces. As the large foot plate sat against the front of the spine, it also served as a fixed reference point to control the depth of drilling. The reaming left two opposed resected arcs, one each, from the opposed vertebral surfaces. The tubular drill guide, which was placed only

preliminary to the drilling, was thereafter completely removed. A cylindrical bony dowel, significantly larger in diameter than the hole formed, was then pounded into the hole already drilled. Cloward's method of instrumentation was designed for, and limited to, use on the anterior aspect and in the region of the cervical spine only. The hole was midline, which would preclude its use posteriorly where the spinal cord would be in the way.

Brief Summary Paragraph Right (49):
As the bone graft to be inserted in Cloward's method was necessarily larger in diameter than the hole drilled, the graft could not be inserted through the drill guide. This mandated the removal of the drill guide and left the graft insertion phase completely unprotected. Thus Cloward's method and instrumentation was inappropriate for posterior application.

Brief Summary Paragraph Right (57):
The apparatus and method of the present invention for preparing the vertebrae for insertion of the implant allows for the rapid and safe removal of the disc, preparation of the vertebrae, performance of the fusion, and internal stabilization of the spinal segment.

Brief Summary Paragraph Right (59):
In the preferred embodiment two distractors are used to separate two adjacent vertebrae to a preferred distance. A hollow Outer Sleeve having teeth at one end is driven into the adjacent vertebrae on one side to hold the vertebrae in position when the distractor is removed, a diameter reducing hollow Inner Sleeve is introduced into the Outer Sleeve, a drill having a drill stop is passed through the hollow Inner Sleeve to drill a hole to a desired depth, and an implant is inserted in the hole. The method is repeated on the other side of the disc.

Brief Summary Paragraph Type 1 (5):
5. Failure to determine the optimal amount of distraction prior to drilling;

Brief Summary Paragraph Type 1 (6):
6. Inability to optimize the amount of distraction so as to restore the normal spatial relationships between adjacent vertebrae;

Brief Summary Paragraph Type 1 (9):
9. The inability to insure equal bone removal from the opposed vertebral surfaces; and

Brief Summary Paragraph Type 1 (17):
7. The present invention holds the vertebrae to be fused distracted throughout the procedure.

Brief Summary Paragraph Type 1 (25):
15. The design and use of a second or Inner Sleeve in the present invention allows for the difference in size between the inside diameter of the Outer Sleeve, and the outside diameter of the drill itself. This difference being necessary to accommodate the sum of the distraction to be produced, and the depth of the circumferential threading present of the implant.

Brief Summary Paragraph Type 1 (26):
16. In the present invention a specially designed drill bit with a central shaft recess allows for the safe collection of the drilling products, which can then be removed without disturbing the Outer Sleeve by removing the drill bit and Inner Sleeve as a single unit.

Brief Summary Paragraph Type 1 (29):
19. In the present invention a specially designed driver extractor, which attaches to the implant and allows the implant to be either inserted or removed without itself dissociating from the implant, except by the deliberate disengagement of the operator.

Brief Summary Paragraph Type 1 (31):
21. The Distractor in the present invention is self-orienting acting as a directional finder.

Brief Summary Paragraph Type 1 (32):
22. The Distractor in the present invention is self-centralizing between the opposed

vertebral surfaces acting as a centering post for the subsequent bone removal.

Brief Summary Paragraph Type 1 (33):
23. In the present invention predistraction assures the equal removal of bone from the adjacent vertebral surfaces.

Brief Summary Paragraph Type 1 (36):
26. In the present invention predistraction allows for the determination of the optimal distraction prior to drilling.

Drawing Description Paragraph Right (2):
FIG. 1 is a side view of the Long Distractor, of the present invention inserted into the intervertebral space.

Drawing Description Paragraph Right (3):
FIG. 2 is a side view of a Convertible Distractor assembly in relation to the spine.

Drawing Description Paragraph Right (4):
FIG. 3 is a perspective view of a high retention Short Distractor of FIG. 2.

Drawing Description Paragraph Right (5):
FIG. 3A is a side view of the high retention Short Distractor of FIG. 2.

Drawing Description Paragraph Right (6):
FIG. 3B is a side view of an alternative Short Distractor with circumferential forward facing ratcheting.

Drawing Description Paragraph Right (7):
FIG. 3C is a top view of the alternative Short Distractor of FIG. 3B.

Drawing Description Paragraph Right (8):
FIG. 3D is a perspective view of an alternative embodiment of a Short Distractor.

Drawing Description Paragraph Right (9):
FIG. 3E is a top view of the alternative distractor of FIG. 3D.

Drawing Description Paragraph Right (10):
FIG. 3F is a side view of a further alternative rectangularized Short Distractor with knurled surfaces.

Drawing Description Paragraph Right (11):
FIG. 4 is a perspective view of a spinal segment (two vertebrae and an interposed disc) with a Short Distractor in place, with a portion of the upper vertebrae and disc cut away to show the Short Distractor on one side of the spine and the Long Distractor about to be placed contralaterally.

Drawing Description Paragraph Right (12):
FIG. 5 shows a side view of the Outer Sleeve in place over the Long Distractor, and about to receive the Driver Cap in preparation for being seated.

Drawing Description Paragraph Right (13):
FIG. 6 shows the Long Distractor, Outer Sleeve, and Driver Cap following the proper seating of the Outer Sleeve into the two adjacent vertebrae.

Drawing Description Paragraph Right (14):
FIG. 7A is a side view of the cervical Outer Sleeve being placed over a Long Distractor which is in place within the disc space anteriorly.

Drawing Description Paragraph Right (18):
FIG. 7E is a bottom view of a Dual Driver Cap for driving two distractors.

Drawing Description Paragraph Right (19):
FIG. 7F is a side sectional view showing the Dual Outer Sleeve of FIGS. 7C and 7D, Distractors and Dual Cap of FIG. 7E seated.

Drawing Description Paragraph Right (20):
FIG. 8 is a side view of the Outer Sleeve of FIG. 7A centered on the Long Distractor and fully seated on the anterior aspect of the cervical spine.

Drawing Description Paragraph Right (21):
FIG. 9 is a perspective view of the Distractor Puller.

Drawing Description Paragraph Right (22):
FIG. 10 is a cutaway partial side view of the Proximal Puller engaging the extraction ring of the Long Distractor over the end of the Outer Sleeve.

Drawing Description Paragraph Right (23):
FIG. 10A is a side view of the Puller coupled to the Long Distractor just prior to its extraction.

Drawing Description Paragraph Right (24):
FIG. 10B is a posterior view of the proximal Outer Sleeve and a Short Distractor in place in regard to the vertebrae, disc and nerves.

Drawing Description Paragraph Right (26):
FIG. 11B is a sectional side view of preparation of the intervertebral space by the alternative "Trephine Method" showing the Distractor, Trephine, Inner Sleeve, and Outer Sleeve in place.

Drawing Description Paragraph Right (27):
FIG. 11C is a sectional side view as in FIG. 11A, but showing the use of an alternative drilling conformation wherein the extended proximal portion is both distracting and self-centering.

Detailed Description Paragraph Right (1):
The following discussion will be in regard to application in the lumbar spine via the posterior approach. In its simplest form, the method of the present invention involves the following steps. The patient is placed on a spinal surgery frame, which allows for the distraction and alignment of the disc space to be fused. A bilateral posterior exposure of the interspace, with or without partial discectomy is then performed. Utilizing distractors the disc space is distracted, and a hollow Outer Sleeve is fitted over one of the distractors. The end of the Outer Sleeve has teeth for engaging the two adjacent vertebrae. The Outer Sleeve is driven into the vertebrae and the distractor is then removed. A hollow Inner Sleeve is then inserted into the Outer Sleeve and a stopped Drill is utilized to prepare the opposed vertebral surfaces. The Drill and the Inner Sleeve are removed as a single unit. The space is tapped if so required. The prepared spinal implant is then inserted via the Outer Sleeve utilizing a stopped inserter. The instruments are then removed and the procedure repeated on the contralateral side of the spine.

Detailed Description Paragraph Right (2):
Step 1a. Prior to surgery, translucent implant templates appropriately adjusted for scale are superimposed on AP, lateral, and axial images of the interspace to be fused, for the purpose of selecting the optimal implant size and to determine the desired distraction.

Detailed Description Paragraph Right (3):
Step 1b. The patient is preferably placed onto a spinal surgery frame capable of inducing both distraction and vertebral alignment.

Detailed Description Paragraph Right (4):
Step 2. In the preferred embodiment, a standard bilateral (partial) discectomy is performed and any posterior lipping of the vertebral bodies adjacent the interspace is removed. Alternatively, no disc material need be removed. In the preferred embodiment, the interspace is exposed by performing bilateral paired semihemilaminotomies and resecting the inner aspects of the facet joints adjacent the spinal canal while preserving the supra and interspinous ligaments.

Detailed Description Paragraph Right (5):
Step 3. Beginning on the first side, the dural sac and traversing nerve root at that level are retracted medially and a Long Distractor then inserted and impacted flush to the posterior vertebral bodies adjacent that interspace. Long Distractors with working ends of increasing diameter are then sequentially inserted until the optimal distraction is obtained. This optimal distraction not only restores the normal height of the interspace, but further achieves a balance wherein the tendency for the space to collapse is resisted, which in urging the vertebral bodies apart is being equally resisted by the powerful soft tissue structures about the spinal

segment including the outer casing of the disc (the annulus fibrosus), various ligaments, capsular structures, as well as the muscles and other soft tissue structures. This balanced distraction not only provides for the spatial restoration of the height of the interspace, but for considerable stability as the space now resists further distraction or collapse.

Detailed Description Paragraph Right (6):
In the preferred embodiment, as the desired distraction is approached, the use of the solid bodied Long Distractors is terminated and a disassemblable Convertible Distractor is placed with tactile and/or radiographic confirmation of ideal distraction. The Convertible Distractor is then disassembled such that the Short Distractor portion is left in place and the ultra-low profile head portion being positioned adjacent to the canal floor and safely away from the neural structures. To insure that the Short Distractor remains in place until its removal is desired, various embodiments of the Short Distractor are available with varying degrees of resistance to dislodgment. In the preferred embodiment of the procedure, attention is then directed to the contralateral side of the spine.

Detailed Description Paragraph Right (7):
Step 4. On the contralateral side of the same interspace the Long Distractor having at its working end the diameter matching the Short Distractor already in place, is then inserted. If however, due to an asymmetrical collapse of the interspace it is then determined that greater distraction is required on the second side to achieve the optimal stability, then the appropriate Short Distractor would be placed on the second side. Then the Short Distractor would be removed from the first side and replaced with a larger Long Distractor so as to bring the interspace into balance.

Detailed Description Paragraph Right (8):
In an alternative embodiment, the entire procedure is performed on the one side of the spine utilizing only the Long Distractor prior to repeating the procedure on the contralateral side of the spine. While this method can be performed in accordance with the remaining steps as described in the preferred embodiment, when utilized it is best performed using a Trephine which allows the Long Distractor to remain in place, thereby allowing for interspace distraction otherwise provided in the first method by the Short Distractor. This alternative method then requires the use of a Trephine over the Long Distractor in lieu of a reamer and is therefore called the "Trephine Method", which will be discussed in detail later.

Detailed Description Paragraph Right (9):
Step 5. With the Short Distractor in place on the first side of the spine, and the matching Long Distractor in place on the second side of the spine, and with the dural sac and traversing nerve root safely retracted, the Outer Sleeve is placed over the Long Distractor and firmly impacted to its optimal depth using the Impaction Cap and a mallet. The Long Distractor is then removed.

Detailed Description Paragraph Right (10):
Step 6. An Inner Sleeve is then placed within the Outer Sleeve, and the interspace is then prepared on that side by utilizing a Drill, Endmill, Reamer, or Trephine to drill, ream, or cut out the bone to be removed to either side, as well as any remaining interposed discal material. In the preferred method, utilizing a specially designed Endmill-Drill, it and the Inner Sleeve are removed as a unit, safely carrying away the bone and disc debris trapped within them from the spinal canal.

Detailed Description Paragraph Right (14):
Step 9. Using the Driver Extractor instrument, the prepared implant is threaded into the prepared interspace. The instrumentation is removed from that side of the spine and attention is then redirected to the first side of the spine. A small retractor is utilized to move the dural sac and traversing nerve root medially and to protect them and allowing the direct visualization of the retained Short Distractor unit. Without removing the Short Distractor, it is reassembled to its shaft portion, essentially reconstituting itself into a Long Distractor. With the inserted implant now acting as the distractor on the opposite side, the Long Distractor is utilized to guide the Outer Sleeve down where it is impacted as described in Step 5.

Detailed Description Paragraph Right (16):
Through preoperative templating of the patient's anterior posterior, lateral, and axially imaged MRI scan in conjunction with translucent overlays of the various sized implants, the correct implant diameter and length are accurately assessed, as well as the correct amount of distraction needed to restore the interspace to its

premorbid height. The patient is then properly positioned and a bilateral partial discectomy performed via paired semihemilaminotomies.

Detailed Description Paragraph Right (17):
For the purpose of this example, it will be assumed that by preoperative assessment it was determined that the correct implant would have an external diameter of 18 mm and be 26 mm long. Further, the distraction necessary to restore the height of the interspace would be approximately 10 mm. The dural sac and traversing nerve root would then be retracted medially and protected, while a Long Distractor having an outside diameter to the barrel portion corresponding to the implant to be inserted, that is 18 mm, and having a diameter at the working end of perhaps 8 mm, would be inserted. This then being found to be slightly smaller than optimal by direct observation, a Convertible Distractor having in its barrel portion an 18 mm outside diameter, but having in its working portion a 10 mm diameter would then be inserted. Direct observation and/or x-ray then confirming the ideal distraction, the Convertible Distractor would then be disassembled, the barrel and head portion removed, and the Short Distractor portion left deeply embedded and with its flanged head flat against the canal floor and deep to the neural structures. It would then be safe to allow the dural sac and nerve root to return to their normal positions, which would be superficial to the flanged portion of the Short Distractor.

Detailed Description Paragraph Right (18):
Attention would then be directed to the contralateral side. The dural sac and nerve root would then be retracted medially on this second side, and a Long Distractor with an 18 mm diameter barrel portion and a 10 mm working portion would then be inserted into the interspace and driven flush to the bone if necessary, such impaction imploding any osteophytes not already removed, and assuring that the shoulder portion of the barrel comes to lie flat against the posterior aspects of the adjacent bodies. With the dural sac and nerve root still safely retracted, the Outer Sleeve would then be placed over the Long Distractor and utilizing the Driver Cap and a mallet, seated to the optimal depth.

Detailed Description Paragraph Right (19):
In the preferred embodiment, the Long Distractor is then removed and the Inner Sleeve is inserted into the Outer Sleeve. Since the purpose of the Inner Sleeve is to support the drill and allow for the increased size of the implant over the size of the drill, thus making it possible for the insertion of the implant to occur through the Outer Sleeve, the Inner Sleeve therefore measures 18 mm in its outside diameter, and 16.6 mm in its inside diameter. This allows it to fit within the Outer Sleeve, the diameter of which is 18.1 mm and to admit the drill bit which is 16.5 mm in diameter.

Detailed Description Paragraph Right (20):
Following the drilling procedure, the Drill and Inner Sleeve are removed as a single unit with the trapped interposed cartilaginous and bony debris. The depth of drill penetration is preset and limited by the fixed rigid column of the Outer Sleeve. In this example, the space will be prepared to a depth of 28 mm in anticipation of countersinking a 26 mm long implant at least 2 mm. If a Tap were to be utilized, it would be inserted at this time and be appropriate to the minor and major diameters of the implant to be inserted and as with the Drill, controlled for its depth of penetration. The spinal implant would then be prepared for implantation by utilizing a Trephine to harvest a core of posterior iliac bone greater than 30 mm long and approximately 14.5 mm in diameter.

Detailed Description Paragraph Right (21):
Using the Bone Loading Device, this core of bone would be forcefully injected into the internal chamber of the spinal implant which would then be capped. Cap end forward, the fully loaded implant would then be attached to the Insertion Driver, down the Outer Sleeve and screwed into place with the depth of penetration limited by the Insertion instrument. The Insertion Driver is then unscrewed from the implant and removed from the Outer Sleeve. With the dural sac and nerve root retracted and protected, the Outer Sleeve would then be removed. This would complete the fusion procedure on that side, and then as described, the procedure would be repeated on the other (first) side of the same interspace.

Detailed Description Paragraph Right (22):
An alternative and extremely useful method is the "Trephine Method". Its advantages include that it may be used in conjunction with the preferred embodiment substituting the use of a hollow, tubular cutter, called a Trephine for the use of

the Drill in Step 5 of the preferred embodiment. Additionally, it may be utilized so as to obviate the need for the placement of the Short Distractor and to allow the procedure to be effectively performed from start to finish on one side prior to initiating the procedure on the opposite side, and while nevertheless maintaining distraction at the site of the bone removal.

Detailed Description Paragraph Right (23):
The following is a description of the "Trephine Method". Having completed the exposure of the interspace on at least one side, the dural sac and nerve root are retracted. A Long Distractor differing from the Long Solid Bodied Distractor of the preferred embodiment only in that the barrel portion is of a precisely lesser diameter than the spinal implant. As in the preferred embodiment, the Outer Sleeve has an inner diameter only slightly greater than the implant to be inserted. Therefore, at this time, a first Inner Sleeve is inserted into the Outer Sleeve to make up the difference between the outside diameter of the Long Distractor and the inside diameter of the Outer Sleeve. With the Outer Sleeve and first Inner Sleeve thus assembled, they are placed over the Long Distractor and the Outer Sleeve is optimally seated using the Impaction Cap. The Cap and first Inner Sleeve are removed, but the Long Distractor and Outer Sleeve are left in place.

Detailed Description Paragraph Right (24):
With the Long Distractor maintaining optimal distraction and with the Outer Sleeve locking the vertebrae together so as to resist any movement of the vertebrae, a hollow, tubular cutter known as a Trephine is then inserted over the Long Distractor and its barrel portion and within the Outer Sleeve. The Trephine, which is stopped out to the appropriate depth, can then be utilized to cut equal arcs of bone from the opposed vertebral endplates.

Detailed Description Paragraph Right (25):
Alternatively, a second Inner Sleeve may be placed within the Outer Sleeve prior to placing the Trephine over the Long Distractor and within that second sleeve. This second Inner Sleeve would be just greater in its internal diameter than the Long Distractor and just smaller in its outside diameter than the inner diameter of the Outer Sleeve. While it would provide enhanced stability to the Trephine, provision would then need to be made in the way of large flutes passing longitudinally or obliquely along the outer surface of the Distractor to its barrel portion to accommodate the bony and cartilaginous debris generated during the cutting procedure.

Detailed Description Paragraph Right (26):
Following the use of the Trephine to the appropriate depth by either of these methods, the Trephine, the Long Distractor, and the second Inner Sleeve, if utilized, are all removed. Since the Trephine cuts two arcs of bone but does not ream them out, a shafted instrument with a perpendicular cutting portion at its working end is then inserted parallel to the disc space and then rotated through an arc of motion cutting the bases of the two longitudinally cut arcs, thus freeing them for removal through the Outer Sleeve. The space may then be tapped if required, and the implant is inserted as per the preferred method. As already mentioned, the "Trephine Method" can be used with or without the use of the Short Distractor on the contralateral side.

Detailed Description Paragraph Right (28):
The interspace to be fused is adequately exposed and the soft tissues and vital structures retracted and protected to either side. Visualization of the broad width of the interspace anteriorly is made possible by the absence of the neurological structures in relation to this aspect of the spine. The center line of the anterior aspect of the interspace is noted and marked. The disc is removed using first a knife and then curettes and rongeurs as needed. Alternatively, the disc may be left intact to be removed during the drilling stage of the procedure. However, as per the preferred embodiment of the procedure, having removed the great mass of the nucleus and the greater portion of the annulus anteriorly, Long Distractors with progressively increasing diameters to their working ends are inserted into the interspace at a point midway between the central marking line and the lateral extent of the anterior aspect of the spine as visualized.

Detailed Description Paragraph Right (29):
The Dual Outer Sleeve with its common Foot Plate and Retention Prongs is then inserted over either a singly placed Long Distractor and then the second Distractor placed, or is placed over both Distractors if already placed. The Dual Outer Sleeve

is then seated firmly against the anterior aspect of the spine. Any spurs which would interfere with the flush seating of the Foot Plate to the anterior aspect of the spine should be removed prior to inserting the Long Distractors. Once the Outer Sleeve has been optimally seated, one of the Long Distractors is removed and in its place is inserted an Inner Sleeve and drill bit. The drill bit has as its outside diameter the minor diameter of the implant to be inserted. The Inner Sleeve is essentially equal in thickness to the difference between the minor and major diameters of the threaded implant.

Detailed Description Paragraph Right (30):
A Stopped Drill is then utilized to prepare the opposed vertebral surfaces and to remove any remaining disc material interposed. If required, a Stopped Tap may be inserted through the Outer Sleeve and into the interspace to create a thread form. The properly prepared implant is then affixed to the Insertion Driver and passed through the Outer Sleeve down into the interspace and inserted until its depth of penetration is limited by the stop on the Insertion Driver. With the implant itself now in a position to act as a distractor, the Long Distractor is then removed from the contralateral side and the procedure repeated. When both implants are firmly in place, the outer sleeve may then be removed. The amount of countersinking of the implants may then be adjusted under direct vision.

Detailed Description Paragraph Right (31):
In the preferred embodiment, the disc (D) between adjacent vertebrae (V) is approached via bilateral paired semihemilaminotomies of the adjacent vertebrae. In the preferred embodiment the supraspinous ligament, the interspinous ligament, the spinous process, portions of the lamina, and most of the facet joints are preserved. However, while less desirable, these structures may be removed.

Detailed Description Paragraph Right (33):
Referring now to FIG. 1, preferably after removing some portion of nuclear disc material, a Long Distractor 100 is inserted under direct vision into the intervertebral space. The disc penetrating portion 102 is essentially cylindrical with a bullet-shaped front end 103 and a shoulder portion 104 where the penetrating portion 102 extends from barrel 106. The penetrating portion 102 urges the vertebral bodies apart, facilitating the introduction of the instruments. Long Distractors with sequentially increasing diameter penetrating portions 102 are then introduced. As the optimal diameter of penetrating portion 102 is achieved, the vertebral bodies to either side are forced into full congruence and thus become parallel, not only to the penetrating portion 102, but to each other. At this time, any remaining excrescences of bone of the posterior vertebral bodies adjacent the posterior disc which have not already been removed are flattened flush to the vertebral body by the forced impaction, such as by hitting with a hammer flat surface 109 of crown 110, driving the shoulder 104 against the lipped portions of vertebrae V. Because of the forced opposition of the vertebral endplates to portion 102 with optimal distraction, unit 100 will then come to lie absolutely perpendicular to the plane of the posterior bodies and absolutely parallel to the vertebral endplates, allowing optimal alignment for the procedure to be performed.

Detailed Description Paragraph Right (34):
Penetrating portion 102 is available in various diameters, but all are of a constant length, which is less than the known depth of the interspace. This combined with the circumferential shoulder 104, which is too large to fit within the interspace, protects against the danger of overpenetration. Barrel 106 is of the same diameter as the external diameter of the device to be implanted. A recessed portion 108 below the crown 110 allows for the Long Distractor 100 to be engaged by an extractor unit shown in FIG. 9.

Detailed Description Paragraph Right (35):
In the preferred embodiment, a Convertible Long Distractor 113 is used on the first side of the spine. As shown in FIGS. 2, the Convertible Long Distractor 113 has a barrel portion 152 separable from the Short Distractor portion 120. While the initial distraction may be performed with a solid Long Distractor, as the optimal distraction is approached the appropriate Convertible Long Distractor is utilized. The Convertible Long Distractor 113 consists of a Short Distractor portion 120 and a barrel 152 having a rectangular projection 134 at one end. The Short Distractor 120 has an increased diameter head 128, a rectangular slot 118 and an internal threaded opening 114. The barrel 152 is hollow and has an internal shaft 111 terminating in a large diameter hexagonal crown 115 at one end and a reduced diameter portion 112. The crown has a detent portion 117 in its flat surface. The other end of the shaft

111 has a threaded small member 116 that corresponds to threaded opening 114. The shaft 111 is prevented from removal from the barrel 152 by set pin 119 passing through the wall of barrel 152 in a convenient manner. The Short Distractor portion 120 is removably attached to the barrel portion 152 via the mating of female rectangular slot 118 and the male mating member 134. The mating held together by utilizing knob 136 to drive the crown 110 connected to interior shaft 111 having a threaded working end screw 116 that threads into the female aperture 118 of the Short Distractor portion 120.

Detailed Description Paragraph Right (37):
The Short Distractor portion 120 of FIGS. 2, 3, and 3A-3F are designed to provide for high stability when temporarily situated so as to resist inadvertent migration while the surgeon is working on the second side. To that end, the embodiment of the Short Distractor 120 shown in FIGS. 3 and 3A has a pair of sharp pegs 126, to embed into the opposing vertebral bodies and forward facing ratchetings 124, that further resist backward movement. FIGS. 3B and 3C, which show the preferred embodiment, are side and top views of an alternative embodiment of the distractor portion such that the distractor portion to be interposed between the vertebrae is essentially cylindrical, but with circumferential forward facing ratchetings 124.

Detailed Description Paragraph Right (38):
A further alternative embodiment is shown in FIGS. 3D and 3E. This is a more rectangularized design, with forward facing ratchetings, without the sharp prongs 126 of FIG. 3. FIG. 3F is a side view of a further embodiment of the Short Distractor 120 shown with knurling, to increase the interference with the bone surface so as to add stability to the unit and to resist dislodgment. To this end, it is apparent that the working ends of both the Long and Short Distractors can have a variety of configurations consistent with their purpose, and that surface irregularities as well as the shape of the ends themselves, with or without prongs 126, may be utilized to make the Short Distractor 120 more resistant to migration.

Detailed Description Paragraph Right (39):
Once the ideal distraction has been achieved on the first side of the spine, the Convertible Distractor is dissociated, leaving Short Distractor 120 in place with its rounded external end 128, safely on the canal floor and deep to the dural sac and nerve root.

Detailed Description Paragraph Right (40):
As shown in FIG. 4, the surgeon then moves to the other side of the spine at the same disc (D) level, and retracts the dural sac and nerve root medially, exposing the disc on that side. Long Distractors 100 are then sequentially inserted into the disc space until the diameter of the distractor on the second side is at least as big as that on the first side. If because of some asymmetry of the interspace a larger diameter distractor is required on the second side to achieve the ideal distraction as compared to the first side, then the second side is fitted with a Short Distractor of the larger diameter, and the surgeon would then return back to the first side. In that event, the first side Short Distractor would then be removed and the Long Distractor 100 corresponding to the increased diameter of the already placed Short Distractor 120 would then be inserted. In either event, the operation is continued by working on the one side where the Long Distractor is in place. In this regard, it should be noted, that by the use of such a device as the Michelson Spinal Surgery Frame, it may be possible to obtain adequate distraction preoperatively such that the surgeon is either disinclined to use a distractor, or to simply place the correct Long Distractor on the first side and then proceed with the surgical procedure on that side before moving to the opposite side. These variations are within the scope of the present invention.

Detailed Description Paragraph Right (41):
The Long Distractor now serves as both a centering post and an alignment rod for the hollow Outer Sleeve 140 shown in FIG. 5 which is fitted over the Long Distractor 100, shown by phantom lines 101 in FIG. 5. The Outer Sleeve 140 is metal and has a sharp toothed front end 142 that is capable of penetrating into and holding fast the two adjacent vertebrae (V). Interrupting the circumferential sharp teeth of 142 are flat, planar areas 152 which serve to resist the further insertion of the sharp teeth into the vertebral bodies. The toothed front end 142 of the Outer Sleeve 140 is a continuation of the tubular shaft 144, which in turn is connected to circumferentially enlarged tubular back end 146 having a knurled outer surface 148 for easier manipulation. An alternative embodiment of an Outer Sleeve incorporates an expansile key hole and slot configuration 154 to either side of shaft 144 along

the mid-plane of the interspace and parallel to it such that the end 142 resists the collapse of the vertebrae (V) to either side of the disc (D), but may nevertheless allow for their further distraction, in the event the only diameter or the root diameter of the implant is larger than the hole drilled.

Detailed Description Paragraph Right (42):
A Driver Cap 160 in the form of an impaction cap has at its far end a flat, closed-back surface 162 and at its other end a broad, circular opening. The Driver Cap 160 fits over both the Outer Sleeve 140 and the Long Distractor 100. As the Driver Cap 160 is seated, interior surface 170 circumferentially engages portion 146 of the Outer Sleeve until the back end 172 engages the internal shoulder 164. As mallet blows are applied to surface 162, that force is transmitted via the internal shoulder 164 to the Outer Sleeve 140 via its far end 172, seating teeth 142 into the vertebral bodies adjacent the disc space D and to the depth of the teeth 142 to the flat portions 152. As the Outer Sleeve 140 is advanced forward, crown portion 110 of the Long Distractor is allowed to protrude within the Driver Cap 160 unobstructed until it contacts the interior flat surface 168. Once crown 110 comes into contact with the flat interior surface 168, then further taps of the mallet will not advance the Outer Sleeve, any further motion being resisted by the flat shoulder portion 104 of the Long Distractor abutting the hard surfaces of the posterior vertebral bodies. In this way, the Outer Sleeve 140 is safely and assuredly inserted to its optimal depth and rigidly securing the two opposed vertebrae as shown in FIG. 6.

Detailed Description Paragraph Right (43):
The Cap 160 is then removed and the Distractor Puller 200 of FIG. 9 utilized to remove the Long Distractor 100 from the spine leaving the Outer Sleeve 140 in place. The Distractor Puller 200 has front portion 202, a mid portion 204, and a back handle portion 206. At the front portion 202 of the Distractor Puller 200, a socket 208 is connected to one end of shaft 210 which at its far end is connected to back handle portion 206. The socket 208 has defined within it a cavity 212 that is open at its front end and funnelized on the interior aspect of its sides. The cavity 212 is constructed so that the head of the Distractor Puller 200 and the partially circumferential flange 218 engages the circumferential recess 108 of the Distractor 100. The entrance to cavity 212 is slightly funnelized, and the leading edges of flange 218 slightly rounded to facilitate the engagement of recess 108 and head 110 of Distractor 100, which is further facilitated in that the Driver Cap 160 leaves portion 108 of Distractor 100 precisely flush with the back surface 172 of the Outer Sleeve 140. This provides a large, flat surface 172 to precisely guide surface 230 of socket 208, and open portion 212 around head 110 while flange 218 engages recess 108. The springloaded detent ball 228 engages hemispherical depression 112 in the crown 110, shown in FIG. 2. This springloaded detent 228 in engagement with complimentary indent 218 protects against the inadvertent dissociation of the Long Distractor from the Puller 200 after the Distractor has been removed from within the Outer Sleeve 140 and prior to its removal from the wound. Once out of the body, the two instruments are easily disassociated by freeing the crown portion 110 from cavity 212 by a manual force applied perpendicular to their relative long axes at this location.

Detailed Description Paragraph Right (44):
A cylindrical and free removable weight 216 is fitted around shaft 210 between the front portion 202 and the rear handle portion 206. Gently, but repeatedly sliding the weight 216 along shaft 210 and driven rearwardly against flat surface 228, transmits a rearward vector to proximal end 202 and thereby to the Long Distractor 100 to which it is engaged.

Detailed Description Paragraph Right (45):
Paired extended handle 224 and 226, allow the surgeon to resist any excessive rearward motion as the instrument is used to liberate the Long Distractor 100. Paired handles 224 and 226 are also useful in that they allow a rotational directing of portion 208, via the shaft 210. This allows the surgeon to control and manipulate rotationally the orientation of the opening of cavity 212 to facilitate its application, to the head 110 of the distractor 100.

Detailed Description Paragraph Right (46):
The Distractor Puller 200 is a significant improvement over the alternatives of striking a remover instrument with an independent hammer over the exposed surgical wound, or manually extracting the distractor by forcefully pulling. The use of a free hammer over the open wound is dangerous because the neural structures can be impacted on the back swing which is made even more likely by the effects of gravity

on the mallet head. Manual extraction by pulling is dangerous because of the significant interference fit of portion 102 within the spine such that significant force would be required to remove the Distractor 100, and if force were not coaxial then the Outer Sleeve might be dislodged or misaligned. Further, once the flat portion 102 became free of the interspace, all resistance to withdrawal would be lost and in the face of the considerable force necessary to free it, the Distractor 100 might easily become projectile imparting injury to the patient and/or the surgeon.

Detailed Description Paragraph Right (47):
Once the Long Distractor 100 has been fully removed from the Outer Sleeve 140, the toothed end 142 of the Outer Sleeve 140, working in conjunction with the Short Distractor 120 on the contralateral side rigidly maintains the relative position of the adjacent vertebrae V. Further, since the remainder of the procedure on that side of the spine occurs entirely through the protective Outer Sleeve 140, and as the nerves and dural sac are external to that Outer Sleeve and superficial to the toothed end 142 of the Outer Sleeve 140, which is firmly embedded into the adjacent vertebrae V, the Outer Sleeve 140 serves to insure the safety of these delicate neural structures. Further, since the Outer Sleeve 140 is of a fixed length and rigid, its flat rearward surface 172 may be used as a stop to the advancement of all instruments placed through the Outer Sleeve 140, thus protecting against accidental overpenetration. Further, the Outer Sleeve 140 assures that the further procedure to be performed will occur coaxial to the disc space D and further, be symmetrical in regard to each of the opposed vertebral surfaces.

Detailed Description Paragraph Right (48):
FIG. 10B is a posterior view of the spine at this stage of the procedure, showing a Short Distractor 120 in place on one side of the spine and the bottom portion of Outer Sleeve 140 in place on the opposite side of the spine.

Detailed Description Paragraph Right (54):
If a larger Outer Sleeve 140 were utilized absent the Inner Sleeve 242, then the Drill 240 would be free to wander within the confines of that greater space and would not reliably make parallel cuts removing equal portions of bone from the adjacent vertebrae V. Further, the bone removal not only needs to be equal, but must be correctly oriented in three dimensions. That is, the path of the Drill 240 must be equally centered within the disc space, parallel the endplates, and parallel to the sagittal axis dissecting the interspace.

Detailed Description Paragraph Right (55):
A further purpose of the Inner Sleeve 242 is that it may be removed simultaneously with the Drill 240, thereby trapping the debris, both cartilaginous and bony generated during the drilling procedure, which are guided rearward by the large flutes 251 of Drill portion 250, where they are collected around recessed portion 256 between the recessed portion 256 and the inner wall of the Inner Sleeve 242 are there contained therein. Thus, by removing the Drill 240 in conjunction with the Inner Sleeve 242, all of the debris generated by the reaming procedure is safely removed from the spinal canal and wound area.

Detailed Description Paragraph Right (56):
Further, if the disc tissue in the area to be reamed has been removed previously, as per the preferred method, then the patient's own bone of good quality and useful within the operation will then be contained between the Inner Sleeve 242 and the shaft portion 256. Once away from the surgical wound, this material may be used to load the spinal implant or placed deep within the interspace to participate in the fusion.

Detailed Description Paragraph Right (57):
The method of actually producing the surgical hole within the spine is variable. As shown in FIG. 11C, in an alternative embodiment Drill end 250 has a forward projecting nipple 260, which itself is bullet-shaped in its leading aspect so as to ease its entrance into the disc space and to urge the vertebrae apart. Nipple 260 is distracting, stabilizing as it resists any tendency of the vertebrae to move together, is self-centering to the Drill portion 250 when working in conjunction with Sleeves 140 and 242, and virtually assures the symmetrical resection of bone from the opposed vertebral surfaces.

Detailed Description Paragraph Right (58):
The alternative "Trephine Method" referred to earlier in this application, is shown

in FIG. 11B. In this alternative, a Long Distractor 100 is left in place after the Outer Sleeve 140 is seated. The Long Distractor 100 in this case differs from the Long Distractor of the preferred embodiment in that its outside diameter of the barrel 106 is of a smaller diameter than in the prior version. This is made necessary because regardless of the method, the hole to be formed corresponds to the minor diameter of the spinal implant. Trephine 270, a hollow, tubular member with sharp cutting teeth 251 at its proximal end, has a wall thickness and since the outside diameter of that trephine 270 must correspond to the root diameter of the implant, then the wall thickness of the trephine 270 must be allowed for by a corresponding reduction in the diameter of the Long Distractor 100.

Detailed Description Paragraph Right (59):
A further modification of the Long Distractor 100 to the "Trephine Method" would use longitudinal grooves (not shown) along the barrel surface 106 for the purpose of transmitting any debris generated during the cutting procedure, rearward. Since the cutting element is both centered and aligned by the Long Distractor, the use of the Inner Sleeve 242 is not mandatory, but may once again be useful in controlling the path of the debris. To that end, little debris is generated in the "Trephine Method" as the bony arcs are not so much being reamed out and removed as they are simply being cut into the bone where these arcs of bone are left connected at their far ends. Thus, when the Trephining Method has been completed and the Trephine 270 and Inner Sleeve 242 removed, unlike in the preferred embodiment where the hole is drilled out, it remains necessary to remove both the two arcs of bone, and any interposed material. Nevertheless, this is very easily performed by various means, one of which is depicted in FIG. 11D.

Detailed Description Paragraph Right (60):
Instrument 272 consisting of a shaft 276 attached off center to the lower surface 273 handle 274. The shaft 274 terminates in a cutting arm 278. The instrument 272 is inserted through Outer Sleeve 140 where the lower surface 273 of handle 274 abuts the top 172 of the Outer Sleeve 140, both stopping downward motion of instrument 272 and precisely placing the perpendicularly cutting arm 278 of instrument 272 so that as handle portion 274 is rotated, the cutting arm 278 is also rotated, cutting the arcs of bone and liberating them from their last attachments. These portions of bone are then removed utilizing this instrument or a long forceps, and then placed within the implants or otherwise used to participate in the fusion.

Detailed Description Paragraph Right (61):
While in the preferred embodiment of the present invention the spinal implant I, is essentially self-tapping, if the bone is unusually hard it may be desirable to form the thread pattern within the interspace prior to the insertion of the implant I. To that end, as shown in FIG. 12, Tap 280 has a threadcutting portion 282 connected by a shaft 286 to a handle portion 292, which has been designed to give mechanical advantage to the rotation of the instrument for the purpose of cutting threads. The lower portion of handle 290 has a forward facing flat surface 288 too large to fit through the opening of Outer Sleeve 140 which thus safely limits the depth of penetration of the cutting element 282. This tap 280 is further made safe by blunt end 294 which will engage the uncut portions of the vertebral bone just prior to the engagement of shoulder 288 against surface 172. This feature allows the surgeon to appreciate a less harsh resistance as the blunt nose 294 encounters the remaining unresected bone for the drill hole and prior to the sudden increase in resistance caused by the seating of shoulder 288 against top edge 172, which first resistance serves as a warning to the surgeon to discontinue the tapping procedure. Thus, the surgeon has both visual (as shoulder 288 approaches top edge 172) and tactile warnings to avoid stripping the thread form. Tap end 282 is highly specialized for its specific purpose. Rearward to the specialized blunt tip 294 is a truncated bullet-shaped area 298 which ramps up to the constant diameter intermediate the cutting ridges 296. Ramp portion 298 urges the opposed vertebral bodies apart, which motion is resisted by Outer Sleeve 140, thus progressively driving the sharp leading edges of thread forms 296 into the vertebral bodies. The periodic longitudinal grooves 284 interrupting the thread forms, which may number 1 to 8, but preferably 4, function to accumulate the bony material which is removed during the thread cutting process. In that regard, in the ideal embodiment, the thread cutting form is designed to compress the bone to be formed rather than to trough through it. Further, while both the major and minor diameters of the Tap 280 may be varied, in the preferred embodiment, the minor diameter corresponds to the minor diameter of the implant I, but the major diameter is slightly less than the major diameter of the implant.

Detailed Description Paragraph Right (62):
With Tap 280 now removed, and Sleeve 140 still in place, the surgical site is now fully prepared to receive the spinal implant I. In the preferred embodiment of the spinal implant, the implant has been enhanced by the use of, application to, and filling with fusion promoting, enhancing, and participating substances and factors. Thus, the implant may be fully prepared for insertion as provided to the operating surgeon. However, at the present time, human bone is most commonly used as the graft material of choice, with the patient's own bone being considered the best source.

Detailed Description Paragraph Right (64):
Because of the high interference between the graft and the inner wall of hollow portion 304, and the relative weakness of the cancellous bone being harvested, it is possible to remove the Trephine 300 while still drilling, and to have it extract the core of bone with it. However, in the highly unlikely event that the core of bone would remain fixed at its base, then with the drive mechanism 308 removed, a corkscrew 408 shown in FIG. 14C is introduced though the central opening of rear portion 306 and threaded down and through the core of bone within 304 and to the depth of teeth 302. The tip 318 of the corkscrew 408, which extends substantially on line with the outer envelope of the corkscrew, then cuts radially through the base of the bone core. As the handle portion 314 of the corkscrew 408 abuts the flat, rearward surface of portion 306 and it can no longer advance. As corkscrew 408 is continued to be turned further, it will cause the core of bone to be pulled rearward, as in removing a cork from a wine bottle. Trephine 300 has a barrel portion 304 continuous with sharp toothed portion 302 having an inner diameter just less than the inner diameter of the spinal implant I to be loaded.

Detailed Description Paragraph Right (68):
End plug 324 is then removed from apparatus 320. Using end plug 324 as a handle, end cap 374 shown in FIG. 16 is secured to the open end of the spinal implant I. The implant is then disassociated from end plug 324 by rotating knob 334 counterclockwise.

Detailed Description Paragraph Right (69):
FIG. 16 shows an Implant Driver instrument which may be used to either insert or to remove said implant I. Driver 350 has at its far end 362, a rectangular protrusion 398, which protrusion intimately engages the complimentary rectangular slot 364 of implant I. Protruding from slot 398 of end 362 is threaded portion 353, which extends as a rod through hollow shaft 358 and hollow hand barrel 360 to knob 354 where it can be rotationally controlled. Threaded portion 353 screws into a female aperture central slot 364, urging 353 into 364, and binding them together such that instrument 350 can be rotated via paired and diametrically opposed extending arms 366 and in either direction while maintaining contact with the implant.

Detailed Description Paragraph Right (72):
Once the implant has been fully installed, the Driver 350 is dissociated from the implant by turning knob 354 in a counterclockwise direction. The Driver 350 is then withdrawn from the outer sheath, then the Outer Sleeve 140 is removed. This leaves the implant fully installed and inset to the determined depth as shown in FIG. 18.

Detailed Description Paragraph Right (73):
Attention is then redirected to the other, or first, side of the spine. A dural nerve root retractor is used to retract the neural structures medially, bringing into full view the head 128 of the Short Distractor 120, lying flush on the canal floor. Utilizing apparatus 152, extended screw portion 116 is inserted into the female threaded portion 114 of the Short Distractor 120 as the extended rectangular portion 134 of apparatus 152 is engaged to the female rectangular portion 118 of the Short Distractor 120. Then turning rearward facing portions 108 and 110, utilizing the knob 136 of FIG. 2, the Long Distractor configuration is restored.

Detailed Description Paragraph Right (74):
With the dural sac and nerve roots still retracted and protected, the Outer Sleeve 140 is slipped over the reconstituted Long Distractor and seated using the Driver Cap 162. The entire sequence of events as described for the implantation of the spinal implant I as already placed, is then repeated such that both spinal implants come to lie side by side within the interspace. Though not necessary, circlage or other internal fixation of the levels to be fused may additionally be performed, and then the wound is closed in the routine manner.

Detailed Description Paragraph Right (76):

The interspace to be fused is exposed anteriorly. The soft tissues are withdrawn and protected to either side, and if necessary, above and below as well. It is then possible to visualize the entire width of the vertebrae anteriorly adjacent that interspace. As discussed above, the surgeon has already templated the appropriate patient radiographs to determine the requisite distraction and optimal implant size. In the preferred method, the surgeon then broadly excises the great bulk of the nuclear disc portion. (Alternatively, the disc can be left to be removed via the drill later.) The surgeon then notes and marks a point midway from side to side anteriorly. He then inserts Long Distractor 100 centering it on a point midway between the point just noted and the lateral extent of the intervertebral space visualized anteriorly. The outer barrel portion 106 of the Distractor 100 utilized, will correspond to the outside diameter of the implants to be installed. The Distractor tips 102 inserted are sequentially larger in diameter until the optimal distraction is achieved. This optimal distraction, although suggested by the initial templating, may be visually and tactilely confirmed as performed. When the optimal distraction is achieved, the vertebral endplates will come into full congruence and parallel to the forward shaft portion 102 of the Distractor 100, causing an alteration in the alignment of the vertebrae and a significant increase in the interference fit and pressurization at the tip, such that the instrument becomes exceedingly stable.

Detailed Description Paragraph Right (77):
There is a sensation imparted to the surgeon of the tissues having moved through their elastic range to the point where the two adjacent vertebrae V begin to feel and move as if a single solid. These changes are easily appreciated visually as the vertebrae realign to become congruent to tip 102, and can also easily be appreciated via lateral Roentgenography. However, should the surgeon fail to appreciate that optimal distraction has been achieved and attempt to further distract the interspace, he would find that extremely difficult to do because of the increased resistance as the tissues are moved beyond their range of elastic deformation. Further, there would be no elasticity left to allow the vertebrae to move further apart and the sensation to the surgeon should he attempt to gently tap the oversized Distractor forward with a mallet, would be one of great brittleness.

Detailed Description Paragraph Right (78):
Returning now to the procedure, when the correct intercorporeal Distractor 100 producing the ideal interspace distraction having its barrel portion 106 corresponding to the implant to be installed has been inserted, then its exact duplicate is inserted anteriorly equidistant to the other side of the spine. As the barrel portion 106 of Long Distractor 100 is exactly of the same major diameter as the spinal implant I looking coaxially on end, the surgeon can then asses the anticipated side by side relationship of the dual implants when implanted.

Detailed Description Paragraph Right (79):
As shown in FIGS. 7C and 7D, a Dual Outer Sleeve 340 consisting of a pair of hollow tubes is then introduced over the side by side Long Distractors protruding anteriorly from the spine. The Dual Outer Sleeve 340 is comprised of two hollow tubular members identical in size displaced from each other ideally the sum of the difference between the minor and major diameters of both implants combined, but not less than that difference for one implant, as it is possible to have the threads of one implant nest interposed to the threads of the other, such that they both occupy a common area between them. However, while the preferred embodiment is slightly greater than two times the difference between the major and minor diameters of the implant (the sum of both) the distance may be considerably greater. Whereas in the preferred embodiment extending tubular portions 348 of instrument 340 are parallel, when the area between them 350, is sufficiently great, these elements may be inclined or declined relative to each other such that they either converge or diverge at their proximal ends. Paired tubular structures 348, may be bridged in part or wholly throughout their length, but are rigidly fixed by Foot Plate 344. In its preferred embodiment, a top view shows the Foot Plate to be essentially rectangular, but without sharp corners.

Detailed Description Paragraph Right (81):
As already taught in FIG. 5, the Dual Driver Cap 420 is of the same design as Single Driver Cap 160, in that there is a recess 354 as per 168, allowing the Outer Sleeve to be fully seated without impeding the rearward projection of the Long Distractor unit. However, unlike in Cap 160, area 354 is more relieved as it is unnecessary for the Dual Cap 420 to contact the Long Distractor through portion 110 to inhibit its forward motion, as the Foot Plate 344 functions to that effect. Further, the Dual

Cap 420 for the Dual Outer Sleeve 340 is correspondingly dual itself and engages the rearward facing dual tubular portion 352. Once the Dual Outer Sleeve has been fully seated, the vertebrae adjacent the interspace to be fused are rigidly held via Foot Plate 344 and the prongs 342. Thus, it is possible to remove either one, or if desired, both of the Long Distractor rods utilizing Long Distractor puller 200, as per the method already described. It is then the surgeon's choice to work on one or both sides of the spine. As per previous discussion, the surgeon may drill the interspace utilizing the Inner Sleeve 242 or leave the Long Distractors in place as per the "Trephine Method".

Detailed Description Paragraph Right (82):
Tapping, if necessary, and the insertion of the implants then occurs through the protective Outer Sleeve 340. Once the implants have been fully inserted, the Outer Sleeve is removed.

Detailed Description Paragraph Right (84):
It is anticipated that the surgeon wishing to work deep within the interspace, or preferring the ability to directly visualize the tap being used, or the implant being inserted, may choose to remove the Outer Sleeve after the insertion of the first prosthesis to maintain stability, or prior to that, which while not the preferred embodiments, are nevertheless within the scope of the present invention.

Detailed Description Paragraph Right (86):
As a further alternative, it should be noted that the key element in the anterior method is the use of the predistraction principle, where such distraction is maintained by the Outer Sleeve with or without the Long Distractor. Therefore, once the preparation of the interspace has been completed, while not the preferred embodiment, it is nevertheless within the scope of this invention that one could remove the Outer Sleeve as there are no neural structures requiring protection, and insert the implants directly rather than through the Outer Sleeve.

Detailed Description Paragraph Right (87):
As yet a further alternative of this method, where the height of the distracted interspace is such that the diameter of the implant required to span that height and to embed with sufficient depth into the opposed vertebral bodies is such that it is not possible to place two such implants side by side, then only a single implant which may be of significantly increased diameter, is used and placed centrally within the interspace rather than to either side. The placement of a singular central graft via the present invention method and instrumentation is in keeping with the methods already described and can be performed using either a drill or the "Trephine Method".

CLAIMS:

1. A method for inserting a spinal implant between two adjacent vertebra comprising inserting a spinal distractor in the disc space on one or both sides of the spinal column to provide for proper spacing of the disc space between the vertebra, inserting over the spinal distractor a hollow tubular member having engagement means for engaging two adjacent vertebrae into the vertebrae; removing the spinal distractor from the hollow tubular member; passing a drill through the tubular member to drill a hole in the disc and a portion of the two adjacent vertebrae; removing the drill; inserting an implant in the vertebrae through the tubular member; and then removing said tubular member.

7. The method of claim 1 in which the tubular member has a removable hollow inner sleeve.

13. The method of claim 1 in which the tubular member has a removable hollow inner sleeve.

14. The method of claim 13 in which said hole is drilled through the hollow inner sleeve and said hollow inner sleeve is removed prior to tapping said hole.

17. The method of claim 1 in which one spinal distractor remains in place in the disc while a first implant is being inserted.

18. The method of claim 17 in which said spinal distractor remaining in place includes a barrel portion that is separable from the front portion of the spinal implant in the disc space.

19. A method for inserting a spinal implant between two adjacent vertebra comprising inserting a spinal distractor in the disc on one side of the spinal column to provide for proper spacing of the disc space between the vertebra, inserting over the spinal distractor a hollow tubular member having engagement means for engaging two adjacent vertebrae into the vertebrae; passing a trephine through the tubular member and over the spinal distractor to drill a hole in the disc and a portion of the two adjacent vertebrae; removing the trephine; inserting an implant in the vertebrae through the tubular member; and removing said tubular member.

26. The method of claim 19 in which the tubular member has a removable hollow inner sleeve.

32. The method of claim 19 in which the one spinal distractor remains in place in the disc while the first implant is being inserted.

33. The method of claim 32 in which said spinal distractor remaining in place includes a barrel portion that is separable from the front portion of the spinal implant in the disc space.

35. The method of claim 34 in which the remaining cut bone is removed from the trephine by an apparatus comprising a handle, a shaft, said shaft connected to said handle at one end and having a cutting blade at an angle to said shaft, said shaft connected off centered to the central axis of said handle.

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Brief Summary Paragraph Right (3):
Not all patients with damage or spinal deformities require surgical intervention. However, patients who have failed to respond to conservative treatment and who have demonstrable disc pathology often require surgical correction. Most typically the surgical correction includes a discectomy (surgical removal of a portion or all of the intervertebral disc). Discectomy is often followed by fusion of the adjacent vertebrae. To alleviate the pain, abnormal joint mechanics, premature development of arthritis, and nerve damage, the disc space vacated by the damaged disc must be preserved following discectomy. Therefore, spacers or implants are required between the vertebrae that were adjacent to the resected disc.

Brief Summary Paragraph Right (4):
Current treatment methods have been unable to accurately control the endplate removal using conventionally designed chisels, scrappers and cutters. Use of conventional surgical instruments does not adequately control the depth of cut into the disc space nor provide a means to accurately the countersink the implant into the prepared cavity--particularly for non threaded impacted. Furthermore, current methodologies do not provide sufficient protection of the neural structures during surgery to prevent neural injury

Brief Summary Paragraph Right (5):
Current treatment methods utilize grafts, either bone or artificial implants, to fill the intervertebral space between adjacent vertebrae. It is desirable that these implants not only fill the disc space vacated by the damaged disc, but also restore the disc space height to pre-damaged condition. An implant must be sufficiently strong to bear substantially all the body's weight above the vertebral space where it is inserted. Furthermore, it is desirable to use the implants to promote fusion of the adjacent vertebrae across the disc space and thereby promote mechanical stability. Current methodologies use implants or spacers made of metal, plastic composites or bone. Use of bone implants offers several advantages over artificial spacers or implants. The bones provide an implant having a suitable modulus of elasticity that is comparable to that of the adjacent vertebrae. The bone implants can be provided with voids, which can be packed with cancellous bone or other osteogenic material to promote bone growth and eventual fusion between adjacent vertebrae. Furthermore, implants formed from cortical bone have sufficient compressive strength to provide a biomechanically sound intervertebral spacer while it is slowly being incorporated or absorbed by the body and substituted for the patient's own bone tissue--colloquially referred to as "creeping substitution."

Brief Summary Paragraph Right (6):
While it is desirable to use natural bone grafts as implants, use of bone is often limited because of a small supply of suitable sources. Xenografts from non-humans, animals, suffer from rejection problems once implanted. While measures are being taken to limit the human body's rejection of xenografts, greater success is still achieved with bone obtained from human sources. The best source is an autograft from the patient receiving the graft. Removal of an autograft requires further surgery and is limited in amount and structural integrity by the patient's anatomy. The alternative source of human bone grafts is allografts harvested from human donors. Since the number of people donating tissue to science is small, these bone grafts represent an extremely valuable and rare commodity. Current methodologies for providing cortical bone implant spacers typically require cutting the spacer, usually in the form of a dowel, from the diaphysis of a long bone. Only a certain portion of the diaphysis is sufficiently thick to provide dowels with requisite strength to maintain the intervertebral space. For example, in a human femur only about the middle third of the diaphysis, where the shaft is narrowest and the

medullary canal is well formed, has sufficient bone wall thickness and density to be used to prepare cortical dowels. The suitable portions of the diaphysis are sliced, and then a plug is cut from each slice. The plugs are then machined to form a dowel. Most often the dowel includes the medullary canal to provide a depot for osteogenic material and promote fusion of the adjacent vertebrae. Much of the donor bone is wasted, particularly the remnants of the slices from the diaphysis used to provide the dowels as well as the end portions of the long bone which cannot be utilized. Above and below this middle section of the diaphysis, the walls of the femur bone become thinner because of the separation of the layers of the bone into cancelli. Thus, these portions of the femur are not considered suitable for forming cortical dowels having the required dimensions for inserting into vertebral spaces. Use of these remnants would provide a more efficient use and conservation of a limited and very valuable natural resource of cortical bone.

Brief Summary Paragraph Right (11):
Other instruments included for use in the present invention include scrapers, rotating scrapers, and impacting or "slap" hammers for driving the implants into position. The slap hammer allows for controlled impacting force and removal of the chisel after cutting.

Brief Summary Paragraph Right (12):
Another aspect of the present invention includes a nerve retractor blade assembly for manipulation of neural structures such as the dural sac and traversing nerve root with minimal trauma to the respective structures. The assembly includes a retractor having a channel adapted to receive a retractor blade, a retractor blade and can include at least one pin, preferably two pins, for securely fixing the positioning of the retractor assembly and blade proximal to the intervertebral space. The blade can be adapted for engagement with the retractor and for extending into the intervertebral space to provide anchorage proximal to the disc space, maintain disc height and maintain distraction. The nerve retractor also includes a handle attached at an angle to the channel. In a preferred embodiment, the retractor channel is provided in the form of a concave channel. It is also contemplated that the retractor channel can be formed in a variety of other shapes, for instance, rectangular and broadened V-shaped channels are also included within the present invention.

Brief Summary Paragraph Right (13):
Yet another aspect of the present invention includes a protective guide sleeve. The protective sleeve includes a body having a hollow core for receiving instruments for performing surgery. In addition, the protective sleeve provides a narrow but unobstructed passageway to the intervertebral space and minimizes the area of tissue impacted by the surgery. Preferably the protective sleeve includes a first and a second distractor fin that can be inserted into the intervertebral space to maintain the space height and alignment of the vertebrae. The protective sleeve provides protection for neural structures and prevents encroachment of the neural structures into the surgical area. The protective sleeve allows use of depth stop on surgical tools. Preferably, the protective sleeve includes at least one window to facilitate visualization. The instruments for preparing and inserting spinal fusion implants can be received within the protective sleeve. Such instruments include the implant holder engaged to an implant, the bone chisel, scrapers, and drills provided in the present invention.

Drawing Description Paragraph Right (45):
FIG. 31 is a perspective view of one embodiment of a distractor for use with the present invention.

Drawing Description Paragraph Right (46):
FIG. 31a is a partial perspective view of the distractor tip of the distractor depicted in FIG. 31.

Detailed Description Paragraph Right (13):
Implant holder 50 engaged to implant 10 can be used to insert the implant into the intervertebral space as depicted in FIG. 11. Insertion tube 90 is inserted into disc space 82 in a far lateral PLIF approach that can be used with a transforminal procedure. Implant 10a is depicted as fully seated in a first preformed cavity adjacent to vertebral body 80. In a preferred embodiment, insertion tube 90 is first positioned adjacent the preformed cavity. Insertion tube 90 is adapted to slidably receive implant 10 and implant holder 50. After implant 10 is securely engaged in the preformed cavity, locking pin 58 is released, thereby allowing second branch 54

to pivot away from first branch 52 and release engagement of projections 64, 66, and gripping arms 60 and 62 from the corresponding attachment recesses and indents on implant 10. Insertion tube 90 may be sized to permit movement of the branches therein or may be withdrawn to allow sufficient movement for disengagement. Implant holder 50 and insertion tube 90 are then removed.

Detailed Description Paragraph Right (33):
Any suitable osteogenic material or composition is contemplated, including autograft, allograft, xenograft, demineralized bone, and synthetic and natural bone graft substitutes, such as bioceramics and polymers, and osteoinductive factors. The terms osteogenic material or osteogenic composition used herein broadly include any material that promotes bone growth or healing including autograft, allograft, xenograft, bone graft substitutes and natural, synthetic and recombinant proteins, hormones and the like.

Detailed Description Paragraph Right (39):
The choice of carrier material for the osteogenic composition is based on biocompatability, biodegradability, mechanical properties and interface properties as well as the structure of the load-bearing member. The particular application of the compositions of the invention will define the appropriate formulation. Potential carriers include calcium sulphates, polyactic acids, polyanhydrides, collagen, calcium phosphates, polymeric acrylic esters and demineralized bone. The carrier may be any suitable carrier capable of delivering the proteins. Most preferably, the carrier is capable of being eventually resorbed into the body. One preferred carrier is an absorbable collagen sponge marketed by Integra LifeSciences Corporation under the trade name Helistat.RTM. Absorbable Collagen Hemostatic Agent. Another preferred carrier is a biphasic calcium phosphate ceramic. Ceramic blocks are commercially available from Sofamor Danek Group, B.P. 4-62180 Rang-du-Fliers, France and Bioland, 132 Rou d Espangne, 31100 Toulouse, France. The osteoinductive factor is introduced into the carrier in any suitable manner. For example, the carrier may be soaked in a solution containing the factor. One preferred embodiment contemplates use of OSTEOFIL.RTM. allograph paste sold by Regeneration Technologies, Inc. The allograph paste can be supplemented with a local autograft obtained from the cutting operation.

Detailed Description Paragraph Right (43):
Non-cutting edge 273 is attached to first arm 267. Similarly, non-cutting edge 272 is attached to first arm 269. Non-cutting edges 273 and 272 are positioned to extend distally beyond cutting blades 268 and 270 in a direction parallel to the longitudinal axis. Referring to FIGS. 25b-c, non-cutting edge 273 includes an upper guide portion 296 and a lower guide portion 298 extending at least partially beyond the cutting edges. Similarly, non-cutting edge 272 includes identical upper and lower guiding portions. The guiding portions contact the surface prior to the cutting edges 268 and 269. Preferably the non-cutting edges 273 and 272 of the adjacent vertebrae are rounded to follow the interior surfaces of the opposing end plates of adjacent vertebrae. Thus, the rounded non-cutting edges follow along the surfaces of end plates and center the box cutter within the disc space and the included upper and lower cutting blades 268 and 270 between the two end plates. When the two cutting blades are centered between the opposing endplates, the blades cut equal amounts of bone from each end plate and are prevented from creating a potential offset opening between the endplates, resulting in improper implant placement and excess bone removal, which could increase the risk of implant interface subsidence.

Detailed Description Paragraph Right (44):
Attachment hole 263 in handle 262 of box chisel 260 is provided for attachment of an impact or slap hammer as depicted in FIG. 27. Impact hammers are well known in the art and attachment hole 263 can be provided for attachment to any of the known impact hammers for use with the present invention. In preferred embodiments, slap hammer 310 includes threaded end 320. Threaded end 320 is threadedly engaged in internal threads in 263. Slap hammer 310 includes weight 316 that slides on shaft 314. Use of a slap hammer in accordance with this invention allows for controlled force impacting cutting tool and implants. The slap hammer also provides a means for removal of impacted surgical tools such as the chisel after cutting.

Detailed Description Paragraph Right (47):
Nerve retractor assemble 340 also includes at least one, preferably two, supporting members positioned on opposing sides of channel 352. Preferably channel 352 includes at least one, preferably two, enlarged edges 347 and 349. Enlarged edges 347 and 349

can be adapted for receiving pin drive shaft 334. In addition, enlarges edges 347 are adapted to receive and hold retractor blade 342. Retractor blade 342 may be inserted from the top portion of channel 352 adjacent shoulder 354 and slidably advanced toward distal end 351. Blade 342 is retained in place by enlarged edges 347 and 349, as well as surface 358. Retainer blade 342 further includes a distractor tip 344 sized to be inserted into a disc space to achieve or maintain distraction. It will be understood that the width of tip 344 may be varied depending on the amount of distraction desired. Moreover, while pins 336 and 338 are disclosed for maintaining the position of the retraction assembly, it is contemplated that the engagement of retractor blade 342 in the disc space may be sufficient to hold the retraction assembly without the use of pins 337 and 338.

Detailed Description Paragraph Right (50):
There is also provided in the present invention a distractor as depicted in FIGS. 31 and 31a. Distractor 370 includes coupling 372 attached to one end of shaft 374 and a distractor head 376 disposed opposite coupling 372 on shaft 374. Distractor head 376 is substantially in the form of a wedge shape, wherein distractor tip 379 forms the apex of the wedge. Preferably, distractor tip 379 contains a blunt edge. Distractor head 376 includes large side 380 and a corresponding large side opposite 380 to form the large side of a wedge. The large side of distractor head 376 is defined as having a length illustrated by reference line 384. Similarly, small side 382 and corresponding side opposite 382 form the short or small side of the wedge having a width illustrated by reference line 386. Furthermore, the detractor head includes a series of index markings 378 which index the depth the retractor is inserted into tissue.

Detailed Description Paragraph Right (52):
Round scraper illustrated in FIGS. 32-32f is provided for use with the present invention. Round scraper 390 includes shaft 402 and scraper head 392. Shaft 402 defines a longitudinal axis 391. Scraper head 392 includes a first arm 393 and a second arm 395. Shaft 402 includes a tapered neck 403. First arm 393 and second arm 395 define a cavity 398 for receipt of cutting debris. Attached to first and second arm 393 and 395 are rounded scraper edges 394 and 396. First arm 393 and second armm 395 are attached to curved tip 404. Rounded scraper edges 394 and 396 are backward-facing cutting edges, which can cut bone or other tissue as the round scraper 390 is withdrawn from the disc space. Round scraper edges 394 and 396 are provided to allow simultaneous cutting on opposing surfaces of adjacent vertebral bodies. First arm 393 includes an upper surface 397 and a lower surface 400. Upper surface 397 and lower surface 400 are substantially flat. Second arm 395 includes similar structures. Upper surface 397 and/or lower surface 400 allow for controlled scaping of the disc space by contacting either the upper or lower vertebral body. Furthermore, the flat upper and lower surfaces 397 and 400 and tapered neck 403 are adapted to provide enhanced viewing of the disc space. It is important to be able to view the disc space while positioning the round scraper 390 in the disc space to remove bony tissue. Round scraper 390 is provided for preparing a bottom of the preformed cavity for proper seating of implants as depicted in the present invention.

Detailed Description Paragraph Right (56):
A preferred embodiment of protective guide sleeve 510 is illustrated in FIG. 36. Protective sleeve 510 includes hollow body 512. In preferred embodiments, hollow body 512 is provided in the form of a hollow rectangular tube. Hollow body 512 includes a seating end 516, which is open and provides access to the interior of hollow body 512. Hollow body 512 also includes an opposite end that branches into a first distractor fin 518 and second distractor fin 520 extending from end 517. First distractor fin 518 is provided with inclined surface 526, which tapers to reduce the width of distractor fin 518. Distractor fin 518 furthermore culminates in a first curve tip 522. Second distractor fin 520 also includes an inclined surface 528 and culminates in curve tip 524. Positioned between the seating end 516 and first and second distractor fins 518 and 520 is viewing aperture 514. Viewing aperture 514 is provided for visualization of the interdisc space and viewing the index marks on the instruments that are inserted through the interior core of hollow body 512. Use of protective sleeve 510 allows a surgeon to minimize incised area and exposure of internal tissue during posterior lumbar interbody fusion surgical procedures. The protective sleeve 510 provides protection for neural structures. Furthermore, seating end 516 of protective sleeve 510 provides a surface for engaging depth stops on surgical instruments to control cutting bony surfaces and countersinking implants.

Detailed Description Paragraph Right (73):
The present invention also includes a method for fusing adjacent vertebrae. The patient is placed on the operating table in the prone position with lateral C-arm fluoroscopy. A midline incision provides the approach and exposure of the interlaminar space and facet joints at the affected level, which for this example is L4-5. The soft tissue exposure should also include the pedicle entry zone at L4 with care taken to not disrupt the facet caps or ligaments at L3-4. Exposure of the dura is accomplished in a routine fashion with bilateral hemi laminectomy and medial facetectomy with care to save the morselized bone ships removed during this decompression. After the lateral dura and nerve root traversing the L4-5 level has been exposed on both sides, the facet should be removed laterally so that there is an adequate exposure to the disc lateral to the L5 root bilaterally. An attempt to preserve some component of the L4-5 facet complex should be made if possible. The epidural veins are coagulated over the annulus or herniated disc and any tethering of the L5 root is dissected to allow for sufficient medial retraction of the dura and L5 root.

Detailed Description Paragraph Right (74):
A conventional discectomy is performed by incising the annulus with preferably a 15 scalpel blade and removing this annulus with a discectomy rongeur. This is done bilaterally, and then soft fragments from the intradiscal space or extruded fragments are removed with the discectomy rongeur in a conventional fashion. Loose intradiscal fragments are removed both medially and laterally into a depth of about 30 mm.

Detailed Description Paragraph Right (76):
The disc space is then sequentially distracted until the original disc space height is obtained and the normal foraminal opening accomplished. This is done by inserting a 9 or 10 mm distractor 370 on one side, rotating it, and then taking a distractor 370 1 mm larger and inserting it in the opposite side, rotating it, and then alternating sides until the desired height is obtained. The largest distractors are left in the disc space in the distracted position while continued disc space preparation is performed on the opposite side.

Detailed Description Paragraph Right (77):
Rotating cutter 430 is inserted into the non-distracted side and rotated to remove residual intradiscal material and create a channel in the dorsal-most endplate, removing osteophytes and facilitating placement of the guide tube anchoring fins. The rotating cutter 430 is inserted into a depth of about 30 mm, rotated and carefully lifted out, removing the soft tissue from the disc space. After using this on the left side, the distractor 370 is removed from the right, inserted on the left, distracted, and then the rotating cutter 430 is used on the right side in the same fashion. This is inserted and rotated until there is no further soft tissue removed from the disc space. After removing the rotating cutter, the discectomy ronguers may also be re-inserted to remove residual soft tissue. At this point, the disc space and opening is ready to accept protective sleeve 510.

Detailed Description Paragraph Right (78):
Using fluoroscopic guidance, appropriate size guide sleeve 510 is selected, and with the dura retracted using flat, bayoneted, dura and nerve root retractor, protective sleeve 510 is seated down into the laminectomy defect and first distractor fin 518 and second distractor fin 520 are anchored into the disc space. Using the mallet, the guide sleeve is then impacted securely into the laminectomy opening with caution not to trap dura or the upper traversing root under the protective sleeve end 517. Once this has been seated on the disc space and the seating confirmed using fluoroscopic guidance, distractor 370 is removed from the opposite side, and the nerve root retractor is lifted out as well.

Detailed Description Paragraph Right (79):
The appropriate box chisel 550 is then inserted into the guide tube and with the slap hammer or the mallet is impacted down into the disc space, cutting the tract in the endplate to accept the bone graft. This is done using fluoroscopic guidance to ensure that the upper cutting blades 558 and lower cutting blades 560 enter the disc space and traverse in a parallel fashion to the endplates. The depth of the chisel may be adjusted by rotating depth 562 stop at the top of chisel 550. Once the chisel has been impacted to the desired depth, preferably about 23-28 mm, it is then removed using the slap hammer technique, carefully removing it from the disc space. After removal of the chisel, whose internal cavity 557 may also include disc and endplate material, the discectomy rongeur is inserted down the guide tube to remove

any further residual soft tissue.

Detailed Description Paragraph Right (80):
The side-loading morselized bone graft loader 670 is then loaded with an alloquat of morselized autologous or autograft bone and then inserted into the guide sleeve 510 with the side opening 682 aimed laterally. Once the bone graft loader 670 is fully inserted in the guide sleeve 510, the piston 672 is impacted down the loader shaft 680 delivering the morselized bone laterally. The bone graft loader 670 is then removed in this "delivered position," the piston removed from the loader shaft 680, and the second alloquat of bone inserted in the bone graft loader. The bone graft loader 682 is then again inserted and aimed with the opening 602 aimed medially. When fully inserted, an alloquat of morselized bone is then delivered medially under the midline. The bone graft loader is once again removed, and the disc space is ready to accept the structural allograft.

Detailed Description Paragraph Right (81):
The appropriate-sized implant 210 is then attached to implant holder 570 and the shaft extension 580 is fully extended by turning extension knob 582, seating the graft on the loader firmly. It is then placed in the guide sleeve 510 and impacted into the disc space to the desired depth. The shaft extension 580 is then unscrewed from the graft and then implant holder 570. The guide sleeve 510 is also then removed from disc space and the discectomy and graft site inspected. The epidural space is then temporarily packed with gel foam for hemastasis, and the entire procedure is again repeated on the opposite side.

Detailed Description Paragraph Right (82):
After the interbody grafts have been securely placed and their location confirmed using fluoroscopy, the large rongeur is used to remove the dorsal aspect of the L5 facet joint at the transverse process on the left side exposing the opening to the L5 pedicle. Using a pedicle probe and with fluoroscopic guidance, the trajectory or path of the pedicle is identified, the pedicle probe is removed, and the appropriate-sized tap inserted down the pedicle, followed by the DYNA-LOK.RTM. pedicle screw. This same procedure is repeated at L4 with care taken not to disrupt the facet joint or ligament at L3-4. The lateral aspect of the facet and transverse process at the junction are removed with the rongeur followed by the probe, tap, and then pedicle screw. This is again repeated on the opposite side. When all four screws have been placed, the titanium plate is seated down over the pedicle screws. The residual morselized bone from the laminectomy and facet is packed laterally over the residual facet joint and medical transverse processes and then the locking screws are seated down onto the plate, and pedicle screws tightened to secure the plates to the pedicle screws. If necessary, a compressor is used to place compression forces on the pedicle screws as the nuts are being tightened down. After the nuts have been tightened, the epidural space is once again inspected for appropriate decompression of the L4 and L5 nerve roots, hemastatis is obtained using the gel foam sponge, and then the wound is closed in layers after irrigating with vast tracent solution. Care is taken to close the fascia securely and attach it to the residual spinous process and interspinous ligament if possible.

Detailed Description Paragraph Right (83):
It is understood to those skilled in the art that the above procedure can be directed to a transforminal procedure using a far lateral PLIF approach through the facet joint. Typically the facet joint is removed to provide an approach to the disc space in an oblique orientation relative to the posterior vertebral body. This provides access to the disc space with minimal retraction of the dural structure and nerve roots.

Other Reference Publication (7):
University of Florida Tissue Bank, Inc. "Allograft Catalog" (1998).

DOCUMENT-IDENTIFIER: US 5716415 A
TITLE: Spinal implant

Abstract Paragraph Left (1):
A spinal implant for use in distracting and maintaining spinal disc height while promoting fusion of adjacent vertebrae of a spinal column includes first and second side surfaces extending substantially parallel to each other. Upper and lower surfaces for engaging the adjacent vertebrae extend between the first and second side surfaces and extend from a first end portion to a second end portion of the spinal implant. The spinal implant includes recesses located in the first and second side surfaces for receiving an instrument to rotate the spinal implant. A method of fusing together the adjacent vertebrae using the spinal implant includes removing at least a portion of the spinal disc between the adjacent vertebrae. The spinal implant is inserted between the adjacent vertebrae with the first and second parallel side surfaces facing the adjacent vertebrae. The spinal implant is rotated into a position in which the parallel side surfaces extend from one of the adjacent vertebrae to the other adjacent vertebrae and the upper and lower surfaces engage the adjacent vertebrae.

Detailed Description Paragraph Right (6):
A plurality of openings 56 and 58 extend from the side surface 20 to the side surface 22 to provide for the flow of body fluids and bone growth from one side of the implant 10 to the other side of the implant. The openings 58 are located near the end portion 30 of the implant. The openings 56 and 58 extend perpendicular to the side surfaces 20 and 22. Preferably, there are five openings 56 and two openings 58 extending between the sides 20 and 22. The openings 56 have diameters larger than the diameters of the openings 58. The sizes, shapes, and positions of the openings 56 and 58 may be varied as desired by a surgeon. Although the openings 56 and 58 are shown extending perpendicular to the side surfaces 20 and 22, the openings 56 and 58 may extend at an acute angle to the side surfaces 20 and 22. Also, it is contemplated that the spinal implant 10 may include recesses in the side surfaces 20 and 22 for receiving autograft or allograft bone, bone proteins, bone substitute, or the like instead of or along with the openings 56 and 58.

Detailed Description Paragraph Right (15):
The method of placing the spinal implants 10 between the adjacent vertebrae 12 and 14 to fuse together the adjacent vertebrae will now be described. Most of the spinal disc located between the vertebrae 12 and 14 is removed. The facing surfaces of the vertebrae 12 and 14 are cleaned with a disc shaver and rongeurs. Preferably, an annulus of the spinal disc is left between the vertebrae 12 and 14.

Detailed Description Paragraph Right (16):
The instrument 80 is used to hold a spinal implant 10. The spinal implant 10 is inserted posteriorly, anteriorly, or anterio-laterally as desired by a surgeon between the vertebrae 12 and 14 with the parallel side surfaces 20 and 22 facing the adjacent vertebrae 12 and 14. The implant 10 is shown being inserted posteriorly in FIG. 9. The spinal implant 10 is inserted so that the end portion 32 is near the anterior side of the spinal column 16 and the end portion 30 is near the posterior side of the spinal column. The spinal implant 10 is rotated 90.degree. to the position shown in FIG. 10 so that the teeth 36 on the upper and lower surfaces 24 and 26 engage the vertebrae 12 and 14 and the side surfaces 20 and 22 extend from the vertebra 12 to the vertebra 14. The wedge shape of the spinal implant 10 alleviates the need to distract the posterior portion of the spine segment a large distance and then compress the posterior portion to achieve the required lordosis. The posterior portion only needs to be distracted to the desired interdiscal height.

Detailed Description Paragraph Right (18):

The remaining space between the spinal implants 10 and the adjacent vertebrae 12 and 14 is packed with autograft or allograft bone, bone proteins, bone substitute, or the like. An apparatus for maintaining the vertebrae 12 and 14 in a desired spatial relationship such as that disclosed in U.S. Pat. No. 4,696,290 is attached to the spinal column 16 until the vertebrae 12 and 14 have completely fused together. The apparatus for maintaining the vertebrae 12 and 14 in the desired spatial relationship prevents the spinal implants 10 from moving out of position and the bone graft from falling out of the spaces between the spinal implants and the vertebrae 12 and 14.

Detailed Description Paragraph Right (23):
A relatively large opening 156 extends from the side surface 20a to the side surface 22a. The opening 156 is packed with autograft or allograft bone, bone proteins, bone substitute, or the like and provides for the flow of body fluids and bone growth from one side of the implant 10a to the other side of the implant. The opening 156 extends perpendicular to the side surfaces 20a and 22a and may extend at an angle to the side surfaces. The size, shape, and position of the opening 156 may be varied as desired by a surgeon.

Detailed Description Paragraph Right (26):
The method of placing the spinal implants 10a between adjacent vertebrae to fuse together the adjacent vertebrae is similar to the method of placing the spinal implants 10 between adjacent vertebrae as shown in FIGS. 4-12 and therefore, will not be described in detail. Most of the spinal disc located between the vertebrae is removed. The facing surfaces of the vertebrae are cleaned with a disc shaver and rongeurs. Preferably, an annulus of the spinal disc is left between the vertebrae.

Detailed Description Paragraph Right (29):
The remaining space between the spinal implants 10a and the adjacent vertebrae is packed with autograft or allograft bone, bone proteins, bone substitute, or the like. A suitable apparatus for maintaining the vertebrae in a desired spatial relationship is attached to the spinal column until the vertebrae have completely fused together.

Detailed Description Paragraph Right (35):
A relatively large circular opening 156b extends from the side surface 20b to the side surface 22b. A relatively large rectangular opening 160 extends from the upper surface 24b to the lower surface 26b and intersects the opening 156b. The openings 156b and 160 are packed with autograft or allograft bone, bone proteins, bone substitute, or the like and provide for the flow of body fluids and bone growth through the implant 10b. The sizes, shapes, and positions of the openings 156b and 160 may be varied as desired by a surgeon.

Detailed Description Paragraph Right (38):
The method of placing the spinal implants 10b between adjacent vertebrae to fuse together the adjacent vertebrae is similar to the method of placing the spinal implants 10 between adjacent vertebrae as shown in FIGS. 4-12 and will not be described in detail. Most of the spinal disc located between the vertebrae is removed. The facing surfaces of the vertebrae are cleaned with a disc shaver and rongeurs. Preferably, an annulus of the spinal disc is left between the vertebrae.

Detailed Description Paragraph Right (41):
The remaining space between the spinal implants 10b and the adjacent vertebrae is packed with autograft or allograft bone, bone proteins, bone substitute, or the like. An apparatus for maintaining the vertebrae in a desired spatial relationship is attached to the spinal column until the vertebrae have completely fused together.

L5: Entry 5 of 6 File: USPT Feb 10, 1998

DOCUMENT-IDENTIFIER: US 5716415 A
TITLE: Spinal implant

Abstract Paragraph Left (1):
A spinal implant for use in distracting and maintaining spinal disc height while promoting fusion of adjacent vertebrae of a spinal column includes first and second side surfaces extending substantially parallel to each other. Upper and lower surfaces for engaging the adjacent vertebrae extend between the first and second side surfaces and extend from a first end portion to a second end portion of the spinal implant. The spinal implant includes recesses located in the first and second side surfaces for receiving an instrument to rotate the spinal implant. A method of fusing together the adjacent vertebrae using the spinal implant includes removing at least a portion of the spinal disc between the adjacent vertebrae. The spinal implant is inserted between the adjacent vertebrae with the first and second parallel side surfaces facing the adjacent vertebrae. The spinal implant is rotated into a position in which the parallel side surfaces extend from one of the adjacent vertebrae to the other adjacent vertebrae and the upper and lower surfaces engage the adjacent vertebrae.

Detailed Description Paragraph Right (6):
A plurality of openings 56 and 58 extend from the side surface 20 to the side surface 22 to provide for the flow of body fluids and bone growth from one side of the implant 10 to the other side of the implant. The openings 58 are located near the end portion 30 of the implant. The openings 56 and 58 extend perpendicular to the side surfaces 20 and 22. Preferably, there are five openings 56 and two openings 58 extending between the sides 20 and 22. The openings 56 have diameters larger than the diameters of the openings 58. The sizes, shapes, and positions of the openings 56 and 58 may be varied as desired by a surgeon. Although the openings 56 and 58 are shown extending perpendicular to the side surfaces 20 and 22, the openings 56 and 58 may extend at an acute angle to the side surfaces 20 and 22. Also, it is contemplated that the spinal implant 10 may include recesses in the side surfaces 20 and 22 for receiving autograft or allograft bone, bone proteins, bone substitute, or the like instead of or along with the openings 56 and 58.

Detailed Description Paragraph Right (15):
The method of placing the spinal implants 10 between the adjacent vertebrae 12 and 14 to fuse together the adjacent vertebrae will now be described. Most of the spinal disc located between the vertebrae 12 and 14 is removed. The facing surfaces of the vertebrae 12 and 14 are cleaned with a disc shaver and rongeurs. Preferably, an annulus of the spinal disc is left between the vertebrae 12 and 14.

Detailed Description Paragraph Right (16):
The instrument 80 is used to hold a spinal implant 10. The spinal implant 10 is inserted posteriorly, anteriorly, or anterio-laterally as desired by a surgeon between the vertebrae 12 and 14 with the parallel side surfaces 20 and 22 facing the adjacent vertebrae 12 and 14. The implant 10 is shown being inserted posteriorly in FIG. 9. The spinal implant 10 is inserted so that the end portion 32 is near the anterior side of the spinal column 16 and the end portion 30 is near the posterior side of the spinal column. The spinal implant 10 is rotated 90.degree. to the position shown in FIG. 10 so that the teeth 36 on the upper and lower surfaces 24 and 26 engage the vertebrae 12 and 14 and the side surfaces 20 and 22 extend from the vertebra 12 to the vertebra 14. The wedge shape of the spinal implant 10 alleviates the need to distract the posterior portion of the spine segment a large distance and then compress the posterior portion to achieve the required lordosis. The posterior portion only needs to be distracted to the desired interdiscal height.

Detailed Description Paragraph Right (18):
The remaining space between the spinal implants 10 and the adjacent vertebrae 12 and 14

is packed with autograft or allograft bone, bone proteins, bone substitute, or the like. An apparatus for maintaining the vertebrae 12 and 14 in a desired spatial relationship such as that disclosed in U.S. Pat. No. 4,696,290 is attached to the spinal column 16 until the vertebrae 12 and 14 have completely fused together. The apparatus for maintaining the vertebrae 12 and 14 in the desired spatial relationship prevents the spinal implants 10 from moving out of position and the bone graft from falling out of the spaces between the spinal implants and the vertebrae 12 and 14.

Detailed Description Paragraph Right (23):
A relatively large opening 156 extends from the side surface 20a to the side surface 22a. The opening 156 is packed with autograft or allograft bone, bone proteins, bone substitute, or the like and provides for the flow of body fluids and bone growth from one side of the implant 10a to the other side of the implant. The opening 156 extends perpendicular to the side surfaces 20a and 22a and may extend at an angle to the side surfaces. The size, shape, and position of the opening 156 may be varied as desired by a surgeon.

Detailed Description Paragraph Right (26):
The method of placing the spinal implants 10a between adjacent vertebrae to fuse together the adjacent vertebrae is similar to the method of placing the spinal implants 10 between adjacent vertebrae as shown in FIGS. 4-12 and therefore, will not be described in detail. Most of the spinal disc located between the vertebrae is removed. The facing surfaces of the vertebrae are cleaned with a disc shaver and rongeurs. Preferably, an annulus of the spinal disc is left between the vertebrae.

Detailed Description Paragraph Right (29):
The remaining space between the spinal implants 10a and the adjacent vertebrae is packed with autograft or allograft bone, bone proteins, bone substitute, or the like. A suitable apparatus for maintaining the vertebrae in a desired spatial relationship is attached to the spinal column until the vertebrae have completely fused together.

Detailed Description Paragraph Right (35):
A relatively large circular opening 156b extends from the side surface 20b to the side surface 22b. A relatively large rectangular opening 160 extends from the upper surface 24b to the lower surface 26b and intersects the opening 156b. The openings 156b and 160 are packed with autograft or allograft bone, bone proteins, bone substitute, or the like and provide for the flow of body fluids and bone growth through the implant 10b. The sizes, shapes, and positions of the openings 156b and 160 may be varied as desired by a surgeon.

Detailed Description Paragraph Right (38):
The method of placing the spinal implants 10b between adjacent vertebrae to fuse together the adjacent vertebrae is similar to the method of placing the spinal implants 10 between adjacent vertebrae as shown in FIGS. 4-12 and will not be described in detail. Most of the spinal disc located between the vertebrae is removed. The facing surfaces of the vertebrae are cleaned with a disc shaver and rongeurs. Preferably, an annulus of the spinal disc is left between the vertebrae.

Detailed Description Paragraph Right (41):
The remaining space between the spinal implants 10b and the adjacent vertebrae is packed with autograft or allograft bone, bone proteins, bone substitute, or the like. An apparatus for maintaining the vertebrae in a desired spatial relationship is attached to the spinal column until the vertebrae have completely fused together.